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09/180,132 05/24/99 KIM

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EXAMINER

HM12/0110

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ART UNIT

PAPER NUMBER

1616

DATE MAILED:

01/10/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/180,132

Applicant(s)
Kim et al.

Examiner
Barbara Badio

Group Art Unit
1616



☒ Responsive to communication(s) filed on Nov 15, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-36 is/are pending in the application.

Of the above, claim(s) 3, 8-14, 20-25, and 28-36 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 2, 4-7, 15-19, 26, and 27 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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First Office Action on the Merits

1. Applicant's election with traverse of compound 38 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that prosecution of all of the claims would not place a substantially greater burden on the examiner. This is not found persuasive because examination of all of the claims would require a search of each species claimed. A search of the elected species might not result in a reference against each of applicant's claimed species and, thus, a reference against the elected species might not be applicable to the other species recited by the instant invention. In addition, according to PCT rules, unity of invention is lacking if the compounds defined by the claims lack a significant structural element which qualifies as the special technical feature and defines a contribution over the prior art. The instantly claimed compounds lack a special technical feature which defines a contribution over the prior art compound.

The requirement is still deemed proper and is therefore made **FINAL**.

2. Based on applicant's elected species, the following generic group will be examined in the present application:

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Compounds as recited by the instant claims wherein R¹ is N(CH₃)₂ or NHCH₃; R² is hydroxy or alkoxy; R³ is hydroxy, alkoxy or acyloxy; R⁴ is hydrogen or alkyl and X is oxo.

3. Claims 1, 2, 4-7, 15-19, and 26-27 will be examined to the extent they read on the generic group defined in #2 above. Claims 3, 8-14, 20-25 and 28-36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

W 5. Claims 1, 2, 5-7 and 26-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites R² can be "cypionyloxy". It is not clear what is intended by the above-mentioned term. The specification lacks a definition and thus clarification of the above-mentioned term.

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Note: The examiner was unable to find definition of the term in any chemical dictionary.

Claim Rejections - 35 USC § 102


6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

 7. Claims 1, 2, 6, 7, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Torelli et al. ('695).

Torelli et al. teach a generic group of 19-nor steroid derivatives including 11-substituted-4,9-dienes such as 17 α -hydroxy-17 β -hydroxyacetoxy-11(4-N,N-dimethylaminophenyl)pregna-4,9-diene-3-20-dione (cols. 15 and 16, compound #10). The reference teaches several properties of the compounds including their antiprogestational and progestational activities (col. 38, line 67 - col. 39, line 8). The compound and composition taught by the reference are encompassed by the instant claims.



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Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.


m 9. Claims 1, 2, ^{4 15-}~~5-7~~, 19 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torelli et al. ('695).

Torelli et al. teach a generic group of 19-nor steroid derivatives including 11-substituted-4,9-dienes such as 17 α -hydroxy-17 β -hydroxyacetoxy-11(4-N,N-dimethylaminophenyl)pregna-4,9-diene-3-20-dione (cols. 15 and 16, compound #10). The reference teaches several properties of the compounds including their antiprogestational and progestational activities (col. 38, line 67 - col. 39, line 8).

The instant differ from the reference by reciting compounds not exemplified by the reference. However, Torelli et al. teach an equivalence between various substituents. For example, the reference teaches an equivalence between (1) hydroxy and acyloxy groups in the 17 α -position (col. 3, lines 3-5) and (2) methyl, ethyl, propyl etc. in the 13-position. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those of the instant claims, because an ordinary

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artisan would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole. The motivation to make other species taught by Torelli et al. is based on the desire to make additional compounds useful as taught by the reference.

 10. Claims 1, 2, 4-7, 15-19 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peeters.

Peeters teaches a generic group of 11-substituted steroids, including 11-(4-N,N-dimethylaminophenyl)pregna-4,9-dienes (col. 1, line 54 -col. 2, line 54). The reference teaches the antigluccorticoid property of the compounds and their use in the treatment of anxiety (col. 1, lines 6-8).

The instant claims differ from the reference by reciting a specific species not exemplified by the prior art. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those of the instant claims, because an ordinary artisan would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole. The motivation to make other species taught by Peeters is based on the desire to make additional compounds useful in the treatment of anxiety.

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Telephone Inquiry Contacts

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara Badio whose telephone number is (703) 308-4595. The examiner can normally be reached between 7:30 am and 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.


Barbara Badio
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January 7, 2000